UNIVERSITY OF LEEDS

NHS
The Leeds Teaching Hospitals
NHS Trust

INFORMED

Individualised patieNt care and treatment FOR MatErnal Diabetes

Understanding the glycaemic profile of maternal diabetes using continuous glucose monitoring: intensive glucose profiling to inform patient care and treatment

Participant Information Sheet

Thank you for considering your participation in our study called INFORMED, which is part of a PhD research project at the School of Food Science and Nutrition. We - as research team - would like to provide you with details about the study, what your role will involve, and other key information before you decide.

Please ask us (*contact details at the end of the handout*) if there is anything that is not clear or you would like more information. Take time to decide whether or not you wish to take part.

Study information

What is the purpose of the study?
During pregnancy, a mother's blood glucose level changes constantly across 24-hour period, and is affected by her physical characteristics, lifestyle, and the pregnancy itself. While many factors affect the way babies grow in the womb, one of the easiest to measure and modify, is the amount of glucose that they get from their mother. Uncontrolled or too much glucose in their mother's blood during pregnancy, usually leads to a large baby and can increase the chance of problems during pregnancy, labour, and immediately after birth for both mother and child. Being born too small can also be problematic and has been linked to increases the chances of obesity and type 2 diabetes.

Glucose levels of the mother rise after meal consumption and, if uncontrolled, can contribute to some of these health concerns. While the type of food being eaten is vital, recent studies have shown that other factors (such as age, ethnicity, activity levels, and sleep duration) also play a part. However, despite knowing these factors, we currently do not know how to modify a meal to match a mother's characteristics and how a mother's diet effects glucose levels throughout pregnancy. As part of your routine care you are wearing a continuous glucose monitor. With this study we are investigating the impact of diet and lifestyle effects on glucose control throughout pregnancy as there is currently very little information on how diet and lifestyle affects glucose levels measures during pregnancy.

Therefore, as a first step, we want to monitor and study how 24-hour and mealtime glucose levels change in response to diet and across pregnancy in women with pre-existing type 1 or type 2 diabetes. Most information on glucose control and medical data will be requested via your medical records, if you give us permission for us to access your data. To decrease the burden of participation, we will use existing data as much as possible. However, to be able assess your diet and lifestyle during pregnancy, we will ask you to complete questionnaires via phone calls. These questionnaires are detailed below. None of the information obtained via the questionnaires will be shared with your clinical care team. This data on lifestyle will be anonymised and is solely for the purpose of this study.

Why have I been invited?
We are approaching women with type 1 and type 2 diabetes, who are early in their pregnancy, to help us with this study. You do not have to take part – it is completely up to you — and does not affect the quality of care you receive

from the NHS. Also, if you choose to take part and later decide to withdraw (for any or no reason), it will not affect your quality of care from the NHS.

What could my participation do?

By taking part in this study, you will help us to better understand how glucose levels change during pregnancy in women with type-1 and type-2 diabetes and the role of diet. By knowing this, we can design special diets and nutritional strategies to minimise the chances of babies being exposed to abnormal glucose levels and their risk of future health problems.

What would taking part involve?

Recruitment. As part of the recruitment process, we ask you to complete a screening questionnaire and medical history questionnaire. The screening questionnaire will consist of questions about education and employment level, health status, current diabetes treatment, previous smoking status and alcohol intake, use of supplements, access to internet and your participation in other studies. The medical history questionnaire will enquire about diagnosis of other diseases such as hypertension, asthma etc. This information will be used to check your eligibility and to set up a database of participant characteristics.

Medical information. We ask you to give us consent to access selected parts of your medical record that reflect your general health and the health of your pregnancy (e.g., blood pressure, blood/urine test results, current medication, diabetes related pregnancy outcomes) and your diabetes health risks (e.g., age, body weight, ethnicity). Additionally, once you have given birth, your baby's birthweight, and any pregnancy complications will be copied from your medical records.

Urine samples. You will be providing urine samples regularly during pregnancy to your clinical team. Once they have been tested, rather than throwing them away we would like your consent to keep the remaining sample for future metabolic analysis. These samples will be processed and anonymised with your unique study number by a member of the clinical staff and research team and subsequently transported to the University of Leeds in designated Human Tissue Act approved and compliant facilities for storage and further analysis. Only researchers directly involved in the study will have access to the samples. Results of samples analyses will only be used for the purpose of the research study. Excess of the samples not used in the analysis for this study will be stored long-term at the University of Leeds for future research.

Blood Samples. You will be having blood taken regularly during this pregnancy for your clinical care. On three of your routine visits to the Diabetes in Pregnancy Clinic we would like your consent to take an additional 10ml of blood (the equivalent to approximately two teaspoons) for the study. We will store this to look at molecular and genetic markers that may be involved in metabolism and diabetes later. No infant blood samples are requested. These samples will be collected, processed and anonymised with your unique study number by a member of the clinical staff and research team and subsequently transported to the University of Leeds in designated Human Tissue Act approved and compliant facilities for storage and further analysis. Only researchers directly involved in the study will have access to the samples. Results of samples analyses will only be used for the purpose of the research study. Excess of the samples not used in the analysis for this study will be stored long-term at the University of Leeds for future research.

Glucose Data. We ask for your consent for us to access your clinical glucose data throughout pregnancy. This will require no additional work on your part.

Lifestyle Questionnaires. On three occasions during your pregnancy, at weeks ~10-12, ~18-20, and ~28-34, we will contact you at your convenience by phone or video call to complete some short questionnaires about your habitual physical activity, sleep quality / patterns and mealtimes. Also, following your three clinical visits at week ~10-12, ~18-20, and ~28-34, we will ask you to keep track of your diet for 3 days (2 weekdays and 1 weekend day) using an

online dietary tracker called MyFood24. During the phone call, we will explain you how to use this dietary tracker. The phone calls will last not more than 30 minutes. The dietary tracker will take approximately 10 minutes per day to complete. This data will be anonymised and none of this data will be shared with your clinical care team.

Breakfast replacements. To gain more insight into mealtime glucose responses, we would like you to consider taking part in additional part of the study, where we will provide you with two different breakfast shakes to drink instead of your usual breakfast for 4 days on two separate occasions (one during your 2nd and one during your 3rd trimester). The two different breakfast shakes (e.g. Shake 1 and Shake 2) have the same amount of carbohydrate as that recommended during pregnancy, but one is designed to be absorbed slower, and the other faster so we can see how this affects your glucose measures on the continuous glucose monitor. Dependent on your randomization you will consume Shake 1 for two days followed by Shake 2 or vice versa. They are vegan friendly and adhere to religious requirements. The shakes will be delivered to your home with instructions for you to prepare. You can still participate in the main study without having to take the breakfast shakes.

This study will tell us, in detail previously unseen, how (mealtime) glucose changes across pregnancy and how diet can best be used to manage glucose levels and minimise maternal and infant health risks.

What are the possible risks of taking part?
Although we have designed the meals to not contain allergens and to release the same amount of glucose as you would usually eat for breakfast there is a possibility that you may experience an allergic reaction or higher glucose levels than normal after the standardised meal consumption. We will check that you have no allergies before taking part and ask you to contact the research team if you have these reactions to the meal. You will be advised to monitor and manage your blood glucose levels like you normally would and feel most comfortable with. However, if blood glucose levels surpass >18mmol/L for more than 90-minutes you are advised to administer a corrective dose of insulin or contact your GP/clinical care team and inform a member of the research team via email. The meals are designed to minimize risk of hyperglycaemia. Blood samples are part of your routine clinical care and will be performed by qualified clinical staff, so any discomfort should be minimal.

What are the possible benefits of taking part?
There are no specific benefits to you of taking part, but participating in this study will give us important information about how to assess glucose in relation to personal characteristics, pregnancy outcomes, and newborn health. We anticipate that this will then help us to identify and develop new diet strategies to help women reduce their risk of small or large babies, stillbirths, pregnancy complications, and improve the long-term health of their children.

Further Information

What will happen if I don't want to carry on with the study?
You are free to withdraw at any time without explanation. If you decide not to carry on, it will not affect your care in anyway.

What if something goes wrong?
During the study, you will be covered by the Sponsor's Insurance, the University of Leeds is acting as Sponsor for this study. The University of Leeds has insurance cover in force, which meets claims against it and where those claims arise from the Universities own negligence in its role and activities relating to the study (and which is subject to the terms, conditions and exceptions of the relevant policy). Clinical negligence indemnification will rest with the participating NHS Trust under standard NHS arrangements.

If you are unhappy about any part of the study, you are encouraged to discuss this with the research team or with the Patient Assistance and Liaison Services (PALS) at your hospital. Normal legal processes are also open to you. We foresee minimal risks as most data will be collected from your routine clinical records and specific study risks are limited to questionnaires and meal replacements.

What will happen to my additional blood samples and urine sample?
Your blood and urine samples will be labelled with your unique study number and stored in freezers at the University of Leeds for storage. Analysis of the samples will be undertaken for molecular and genetic factors that may contribute to a mother's metabolism, glucose control and babies growth. Only researchers directly involved in the study will have access to the samples. Results of samples analyses will only be used for the purpose of the research study. Excess of the samples not used in the analysis for molecular and genetic factors will be stored at the University of Leeds in designated Human Tissue Act approved and compliant facilities for long-term storage and future research.

How will we use information about you?
We will need to use information from you and from your medical records (including the continuous glucose monitoring data) for this research project. This information will include your initials/ NHS number/ date of birth/ name/ contact details. This data will be destroyed after the end of the study. Unless, you consented us to keep your contact details to contact you about future studies. This data will be stored securely on University of Leeds password encrypted computers and be destroyed after 5 years. Your study information will be given an unique anonymised study number, so that the study information cannot be linked to your personal information. One member of the research team, who is authorised by the NHS, will be able to access the medical data that you consent to. Only this NHS authorised member of the research team will manage your data on secure university computers. Other members of the research team will not be able to link your contact details and health records. This anonymised research data for analysis, writing up of the results, and study validation will be stored on password encrypted computers and be destroyed after 15 years. We will keep all information about you safe and secure. All analyses and reports will be written in a way that no-one can work out that you took part in the study.

How will my information be kept confidential?
All information which is collected about you will be held securely and treated in accordance with the Regulation (EU) 2016/679 (General Data Protection Regulation) and the Data Protection Act 2018.

We will be using information collected by your local hospital from you and your medical records in order to undertake this study. No personal identifiable data will leave the NHS hospital without your consent; Data leaving the hospital will be labelled with your unique study number and will not have your name or any other identifying details on it. We refer to this as linked anonymised data as it is linked to you by a code. The code will only be known by key research team members, which will be kept securely.

Data which leaves the NHS Trust where you are being treated will be held securely in a database, operated by the data analysis team at the University of Leeds. This includes only linked anonymised study data and will not have your name or any other identifying details on it.

If you join the study, the data collected for the study, together with any relevant medical records, may be looked at by authorised persons from University of Leeds, the Research and Development Department of your local hospital and the Regulatory authorities to check the study is being carried out correctly. They all have a duty of confidentiality to you as a research participant.

Other third party researchers (e.g. universities, NHS organisations or companies involved in health and care research) may wish to access anonymised data (including samples) from this study in the future (anonymised data do not include names, addresses, or dates of birth, and it is not possible to identify individual participants from anonymised data). If this is the case, the Chief Investigator will ensure that the other researchers comply with legal, data protection and ethical guidelines. This may include research outside of the UK and EU and/or research that is commercial in nature. Your data will be stored securely for a period of 15 years after the end of the trial before being destroyed.

What are your choices about how your information is used?

If you withdraw consent during the study, no further data will be collected on you. However, any data (including samples) already collected by the research team may be retained and subsequently analysed for the purposes of the study. Your right to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. To safeguard your rights we will use the minimum personally-identifiable information possible.

The University of Leeds as the Sponsor, is the data controller for this study. This means that we are responsible for looking after your information and using it properly.

The University of Leeds is the data processors for this study. The lawful basis for processing personal data collected in this study is that it is a task in the public interest. You can find out more about how we use your information at https://dataprotection.leeds.ac.uk/wp-content/uploads/sites/48/2019/02/Research-Privacy-Notice.pdf; and https://dataprotection.leeds.ac.uk/wp-content/uploads/sites/48/2019/09/HRA-transparency-wording.pdf. or by contacting University of Leeds Data Protection Officer's (e-mail: dpo@leeds.ac.uk).

What will happen to the study results?
The study is part of a PhD project and the result will be used for writing the doctorate thesis. The study results may be presented at meetings or published in scientific journals but individuals will not be identifiable. After the study has ended we will send a newsletter with the study results to your research team, which they will be able to share with you.

Who is organising and funding the research?
The research study has been primarily funded and sponsored by the University of Leeds with additional support from the Wellcome Trust. The Chief Investigators (Dr Micheal Zulyniak and Professor Eleanor Scott) are University of Leeds researchers. Professor Scott is also one of the senior NHS consultants providing clinical care in the Diabetes Pregnancy Clinic.

Who has reviewed the study?
Before any research goes ahead it has to be checked by an Ethics Committee. This study has been reviewed by the Leeds East Research Ethics Committee.

What happens now if I agree to do the study?
The study procedures will be explained to you in more detail by the research team. You will be able to ask questions and voice any queries. If you agree to take part we will ask you to sign a consent form and complete screening questionnaires online to confirm eligibility, this will take approximately 10 minutes. The research team will then co-ordinate with you the dates for completing the lifestyle questionnaires, food dairy, and consuming the breakfast replacements. If you are not eligible to participate, information provided prior to participation will be destroyed. Unless, you opted 'Yes – My email can be kept on file and I am willing to be contacted about future studies', this information will be destroyed after 5 years.

Please, contact the research team for more information:

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